



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,039	12/15/1999	Rachel Meyers	5800-49	7067

826 7590 01/22/2003

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 01/22/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 19

Application Number: 09/464,039
Filing Date: December 15, 1999
Appellant(s): MEYERS, RACHEL

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed Sept. 30, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 79 and 88-92 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

These rejection is set forth in prior Office Action, Paper No. 13

Claim Rejections - 35 USC § 101

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for the same reasons of record as set forth in the earlier official action mailed on the 08/19/01.

The applicant further argues that 21612 sequence (SEQ ID NO: 8) indicates that 21612 is a member of the short chain-dehydrogenase family of proteins based upon protein family domains analysis in PFAM database (response, page 7-8, ¶ 2). The applicant further argues that based upon homology to existing nucleic acid or proteins the invention as claimed assert a specific substantial and credible utility (response, page 8, ¶ 2).

However, this is found unpersuasive because PFAM analysis revealed that 21612 matches with a top-scoring domain for ADH-short but with a low sequence similarity. The specification fails to disclose that polynucleotide sequences of SEQ ID NO:8 encodes an amino acid sequence which is an human alcohol dehydrogenase (AHD) as shown by structural and/or functional properties. The recited SEQ ID NO(s) are simply computer-generated hypotheses, wherein no biological function has been established. It is known in the art that Alcohol dehydrogenase (ADH) constitutes a complex enzyme system with different forms and extensive multiplicity and the range of the biochemical reactions which can be catalyzed by ADH is extremely wide (Duester, Eur. J. Biochem 267:4315-4324, 2000, see page 4316 table 1, 2, page 4317-4319). The specification fails to show a single working example that establishes that the SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7 is a member of Alcohol dehydrogenase (ADH) family, such as by any substantial sequence homology and/or functional assay of the protein. The only immediate apparent utility for the instant invention would be its further scientific characterization as a putative ADH protein like activity.

Furthermore, One skilled in the art would not readily attribute any ADH-like activity encoded by the instant nucleic acid in view of the low sequence similarity and the lack of sequence conservation therein. At best the Office sequence search using the disclosed amino acid sequences (SEQ ID NO:8) matches with a hypothetical protein belonging to ribitol-dehydrogenase super-family from C. elegans (ACC. No. T19954) and a human alcohol dehydrogenase (ACC. No. AA622988) but with only 41.7% and 12.7% sequence similarity respectively. Further inspection of the comparison shows limited if any areas of conservation between the two sequences. In view of such and the fact that ADH differs substantially in activity, it is unclear that any ADH-like activity could be attributed to the deduced amino acid sequence of the claimed nucleic acid sequences. Therefore, the asserted use for the claimed

Art Unit: 1636

nucleic acid is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene.

Claim Rejections - 35 USC § 112

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons of record as set forth in the earlier official action mailed on the 08/19/01.

The applicant argues that 21612 shares high level of sequence identity with consensus domain that is conserved among members of the short chain dehydrogenase family and the specification teaches methods for determining additional residues that are essential for the protein function. The applicant further argues that the specification provides guidance regarding assays for dehydrogenase activity and one skill in the art would be able to determine the functionality of 21612 variants (response, page 10, ¶ 2-4).

However, this is found unpersuasive for the same reasons of record as set forth the lack of utility rejection above (*supra*). The specification fails to show a single working example that establishes that the SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7 is a member of Alcohol dehydrogenase (ADH) family, such as by any substantial sequence homology and/or functional assay of the protein. It is unclear how one skill in the art would use the invention as claimed when the function of the polypeptide encoded by the nucleotide sequence of SEQ ID NO:8 is not known. In addition, the claimed invention is drawn to the polypeptide encoded by the nucleic acid sequences which hybridize to nucleic acid sequence of SEQ ID NO:8 or have 70-90% sequence identity to SEQ ID NO:8 (see claims 88-90). The variants as claimed encompass 10-30% nucleotide sequence variation over the entire length of SEQ ID NO: 8. The variation also encompasses the conserved motifs that are germane to the ADH specific biological activity. The claimed invention is not enabled in view of lack of teachings in the specification as filed regarding what additional sequences may be added, deleted or substituted to those specifically disclosed, such that asserted utility discussed in the section 101 rejection above would be recognized as specific and/or substantial. The specification as filed only teaches nucleic sequence of SEQ ID NO:8 which encodes the amino acid sequence of SEQ ID NO:7 and it is not even clear whether the SEQ ID NO:8 encodes any alcohol dehydrogenase like activity. In addition, the specification fails to disclose that any and all variants of SEQ ID NO:7 (as claimed) are capable of eliciting any ADH-like activity.

It is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The recited SEQ ID NO(s) are simply computer-generated hypothesis because no biological function has been established. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional

Art Unit: 1636

configuration to be active, which is dependent upon the surrounding residues. Therefore, applicant has not presented enablement commensurate in scope with the claims.

In addition, the specification fails to disclose the role of the claimed polypeptides encoded by SEQ ID NO: 8 in any disease. It is unclear whether the disease would be the result of the loss of 21612-like activity or is the result of altered protein function. It is even unclear whether the treatment of the disease associated with polypeptide as claimed would require increase or decrease in the expression of claimed 21612 protein. Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The quantity of experimentation required would include the functional characterization of polypeptide encoded by SEQ ID NO: 8 as a protein having an alcohol dehydrogenase-like activity and use thereof.

In addition the invention as claimed encompass a host cells in vivo which contains the claimed nucleic acid sequences (see claim 65-67 and 95-97). The applicant argues that vectors and methods of gene therapy and for the production of transgenic animals are well known to those skill in the art and many factors that determine the success of the methods have been identified (response, page 11, ¶ 3). However, this is found unpersuasive because Applicant's argument alone cannot take place of evidence lacking in the record. The art at the time of filing clearly teaches that the Gene therapy is considered highly experimental area of research at this time, and both researchers and the public agree that demonstrable progress to date has fallen short of initial expectations (Rosenberg et al, Science 287:1751, 2000). Similarly, the state of transgenic art at the time of filing was such that phenotype of an animal is determined by a complex interaction of genetics and environment. (Wood. Comp. Med. 50(1): 12-15, 2000, see page12). In addition, the scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Claims 88-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant argues that invention as claimed has been described by both structural and functional properties (i.e. dehydrogenase activity), thereby meets the standard set forth in the "Written description" guidelines. However, this is found unpersuasive because the applicant fails to point out where in the specification it is disclosed that the polypeptide encoded by the nucleic acid molecule of SEQ ID NO: 8 have any alcohol dehydrogenase-like activity explicitly or implicitly as putatively consider by the applicant. The instant claims are drawn to a nucleotide sequence encoding a polypeptide having dehydrogenase activity, wherein the nucleotide has at least 70-90% sequence identity with nucleotide sequence of SEQ ID NO:8. The specification as fails to disclose any and all variant of human alcohol dehydrogenase comprising the nucleic acid sequence of SEQ 8, which encodes the amino acid sequences of SEQ ID NO:7. The specification

Art Unit: 1636

discloses only one variant of ADH-like polypeptide within the scope of genus comprising the claimed SEQ ID NO:8. The specification proposes to discover other members of the genus using hybridization procedure. However, there is no description of mutational sites that exist in nature, and there is no description how the structure of identified nucleic acid sequences relates to the structure of any strictly neutral alleles. The art at the time of filing teaches that ADH-like polypeptides include members that would be expected to have widely divergent functional properties based upon their substrate specificity (Duester, Eur. J. Biochem 267:4315-4324, 2000, see page 4316 table 1, 2, page 4317-4319). At best the specification only disclosed nucleic acid sequence of SEQ ID NO: 8 which encodes the amino acid sequence of SEQ ID NO:7. The specification fails to disclose any and all variants of nucleic and amino acid sequences of SEQ ID NO(s) as claimed. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 is indefinite because it is unclear what are the "instructions for use" in this context. The applicant fails to address this rejection in the response filed on 01/15/02.

(11) Response to Argument

Claim Rejections - 35 USC § 101

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The applicant argues that Pfam analysis demonstrates that 21612 (SEQ ID NO:7) is an ADH short chain dehydrogenase (see Appendix B). The applicant argues that the function of the 21612 was not determined based upon overall sequence identity with proteins, but rather based upon Pfam-analysis. The applicant argues that the nucleotides 27-386 of NCBI Acc. No. AA622988 share 99% sequence identity with nucleotides 1694-2052 of the claimed SEQ ID NO:7. The applicant argues that although polypeptide of NCBI Acc. NO. T19954 shares 41.7% overall similarity with SEQ ID NO:8, it shares approximately 64% local sequence identity and approximately 74% local similarity over amino acids 2-276 of SEQ ID NO:7 which comprises a region containing consensus. The applicant further argues that the function of the 21612 dehydrogenase was determined using Pfam-analysis, which is accepted by those skilled in the art

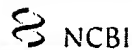
Art Unit: 1636

However, this is not found persuasive because applicant fails to provide a single biological assay, which establishes the amino acid sequences of SEQ ID NO:7 (418 residues long) encodes any ADH short dehydrogenase-like activity explicitly or implicitly as putatively considered by the applicant. Furthermore the applicant fails to establish any nexus between the sequence homology and ADH short dehydrogenase-like activity for the amino acid sequence of SEQ ID NO:7. Even though the applicant asserts that the amino acid sequences of SEQ ID NO:7 contain a ADH short chain dehydrogenase-like motif (pfam 00106), the applicant fails to consider that besides the presence of an ADH short chain dehydrogenase-like motif the amino acid sequence of SEQ ID No:7 also contain a SCP2 domain (Pfam02036) that is involved in the binding of Sterols. (*see US-PTO Pfem-analysis below*).

Considering the presence of two functionally distinct domains the applicant fails to provide any evidence that the amino acid sequences of SEQ ID NO:7 has any alcohol dehydrogenase-like activity based upon any alcohol dehydrogenase specific substrate specificity. The earlier office action clearly provided the evidence that it is known in the art that Alcohol dehydrogenase (ADH) constitutes a complex enzyme system with different forms and extensive multiplicity. (Duester, Eur. J. Biochem 267:4315-4324, 2000, see page 4316 table 1, 2, page 4317-4319, reference of record). The art at the time of filing further teaches that ADHs have wide substrate specificities and are responsible for the metabolism of ethanol, retinoids, and many other alcohols and aldehydes. Furthermore, SDR (short chain dehydrogenase) enzymes typically have subunits containing approximately 250 residues (Duester page 4316). However, in instant case the amino acid sequence of SEQ ID NO:7 is 418 residues long which longer than the predicted SDR length (250 residues). Considering the state of the art and pfam-analysis the applicant fails to provide a single working example that establishes that the SEQ ID NO:7 is a member of SDR family. The applicant even fail to disclose an assay that one skill in the art would use to determine the functional activity of the polypeptide encoded by SEQ ID NO:7. The applicant arguments would be persuasive if they have demonstrated the catalytic oxidation of a single SDR substrate using the claimed amino acid sequences. Therefore, the asserted use for the claimed nucleic acid sequences is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene. At best the only disclosed utility of the invention as claimed would be further scientific characterization of amino acid

Art Unit: 1636

sequences of SEQ ID NO: 8 as i) an ADH short dehydrogenase or ii) a Sterol binding protein and/or iii) a protein with novel characteristics.

Pfam -analysis

NCBI Conserved Domain Search

New Search PubMed Nucleotide Protein Structure CDD Taxonomy Help?

RPS-BLAST 2.2.4 [Aug-26-2002]

Query= local sequence:
(414 letters)

Database: oasis_gap.v1.58
4540 PSSMs; 885,521 total columns

Click on boxes for multiple alignments



Show Domain Relatives

- .. This CD alignment includes 3D structure. To display structure, download [Cn3D!](#)

PSSMs producing significant alignments:

	Score	E
	(bits)	value

- [gnl|CDD|7456](#) pfam00106, adh_short, short chain dehydrogenase. This family c... [102](#) 3e-23
- [gnl|CDD|4671](#) pfam02036, SCP2, SCP-2 sterol transfer family. This domain is ... [76.5](#) 2e-15

- [gnl|CDD|7456](#), pfam00106, adh_short, short chain dehydrogenase. This family contains a wide variety of dehydrogenases.

CD-Length = 252 residues, only 71.8% aligned
Score = 102 bits (255), Expect = 3e-23

Query:	9	AGCTVFITGASRGIGKAI	ALKAARDGANIVA	AKTAQPHPKLL	BGTIYTAAEEIE	AVGGKA	68
Sbjct:	1	TGKVALVTGASSGIGLAI	ARRLAKEGAKVV	VDRREEKAE	-----ALAE	LKAE	53
Query:	69	LPCIVDVRDEQQISAA	VEKAIKKFEGG	IDILVNNASAI	SLTNTLDTPT	KRLDLM	128
Sbjct:	54	LFIQLDVTDEASVKA	AAVAQAVEEL	GRDLVLVNNAG	ILGDGPPFELS	EDDWER	113
Query:	129	TYLASKACIPYLKSK	VAHILNIS	PPLNNPVWF	KQHCA	YTIAGMS	188
Sbjct:	114	VFNLTRAVLPHMLK	GSGGRI	VNVSSVAGL	VPSPGLS	AYSASKAA	172
Query:	189	-IAVNALWP	196				
Sbjct:	173	GIRVNAIAP	181				

- [gnl|CDD|4671](#), pfam02036, SCP2, SCP-2 sterol transfer family. This domain is involved in binding sterols. It is found in the SCP2 protein, as well as the C terminus of the enzyme estradiol 17 beta-dehydrogenase EC:1.1.1.62. The UNC-24 protein contains an SPFH domain pfam01145.

CD-Length = 111 residues, 95.5% aligned
Score = 76.5 bits (188), Expect = 2e-15

Query:	309	EETFRIVKDSLSDDWK	ATQAIYLFELSG	EDG--GTWFLDL	KS	KG	366
Sbjct:	6	QELEEAVKELGEELV	KKVGAILFENV	KDGTGKEDAW	TIDL	KNGK	65
Query:	367	SMTTDDFVKMFSG	KLKPTMAFM	-GKLKIKGN	MALAIKLE	KL	411
Sbjct:	66	SASDSDFLKILTK	GLDPQAFMQG	KLKIKGNM	LAMKLM	AVL	111

Claim Rejections - 35 USC § 112

Claims 63-67, 77-79 and 87-104 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, **to make and/or use the invention.**

The applicant argues that the specification provides sufficient guidance to allow one skill in the art to make and use functional variants of 21612 dehydrogenase by determining percent identity and hybridization under stringent conditions. The applicant further argues that screening the functional variants of a polypeptide is routine in the art and it would not requires undue experimentation to screen the variants of 21612 dehydrogenase. The applicant further argues that there is no requirement that the disclosure provide working example of every permutation of the invention.

However, this is not found persuasive for the same reasons of record as set forth in the rejection under 35 USC § 101, regarding lack of a patentable utility (*supra*). The office has clearly met the burden by establishing that the asserted use for the claimed nucleic acid sequences is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene. The applicant's assertion is mere a computer based hypothesis, since the applicant fails to establish that SEQ ID NO:7 is a member of SDR family by a simple experimentation which demonstrated that the amino acid sequences of SEQ ID NO:8 encodes a polypeptide that catalyzes the oxidation of a single SDR substrate know in the art (see Duester, page 4316, table-2). In addition, considering the pfam-analysis which reveled the presence of additional SCP2 domain (Pfam02036) it is unpredictable that the SEQ ID:7 encodes i) an ADH short dehydrogenase or ii) a Sterol binding protein and/or iii) a protein with novel characteristics. Furthermore, considering the fact that applicant fails to disclose a single assay to determine the biological activity of claimed polypeptide it would requires excessive and undue amount of experimentation to screen any and all variants of 21612 polypeptide, wherein the variants encompasses at least 10-30% variation in the nucleic acid of SEQ ID NO:8 (2535 nt long). The earlier office action clearly states that even conservative amino acid substitutions can

Art Unit: 1636

adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Testing and screening of variant encompassed by the claimed subject matter would clearly require undue experimentation and a methodology never even attempted on the scale. For example, it would require the screening of at least 3.3×10^{10} to 9.8×10^{10} variants of 21612 using unspecified means, since applicant fails to disclose a single assay to determine the biological activity of polypeptide as claimed. Therefore, the experimentation left to those skilled in the art is unnecessarily and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

In addition the applicant argument that the host cells of claims 65-67 and 95-97 are not directed to subject matter related to gene therapy and/or transgenic animals is found unpersuasive because the instant specification clearly disclosed the use of polynucleotides as claimed in constructing transgenic animals (spec. page 68, line 30-31) and in gene therapy (spec. page 79, line 11-15). Therefore the scope of host cell as claimed encompasses a cell in-vivo.

Claims 88-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant argues that the applicant has shown that the 21612 polypeptide has dehydrogenase activity as addressed in the arguments relating to the rejection under 35 USC § 101. The applicant argues that office has provided no evidence to demonstrate that one skill in the art would doubt the credibility of applicant's assertion that the 2162 polypeptide functions as a dehydrogenase. The applicant argues that instant claims provide relevant, identifying characteristics that describe the claimed genus and one skill in the art would recognize that inventors were in the possession of the claimed invention.

However, this is not found persuasive for the same reasons of record as set forth in the rejection under 35 USC § 101, regarding lack of a patentable utility (*supra*). The applicant's assertion is mere a computer based hypothesis, since the applicant fails to establish that SEQ ID

Art Unit: 1636

NO:7 is a member of SDR family by a simple experiment, which demonstrated that the amino acid sequences of SEQ ID NO:8 encodes a polypeptide that catalyzes the oxidation of a single SDR substrate known in the art (see Duester, page 4316, table-2). In addition, considering the pfam-analysis which revealed the presence of additional SCP2 domain (Pfam02036) it is unpredictable that the SEQ ID:7 encodes i) an ADH short dehydrogenase or ii) a Sterol binding protein or iii) a protein with novel characteristics. Furthermore, considering the fact that applicant fails to disclose a single assay to determine the biological activity of claimed polypeptide it would require excessive and undue amount of experimentation to screen any and all variants of 21612 polypeptide, wherein the variants encompasses at least 10-30% variation in the nucleic acid of SEQ ID NO:8 (2535 nt long). Testing and screening of variant encompassed by the claimed subject matter would clearly require undue experimentation and a methodology never even attempted on the scale. For example, it would require the screening of at least 3.3×10^{10} - 9.8×10^{10} variants of 21612 using unspecified means, since the applicant fails to disclose a single assay to determine the biological activity of polypeptide as claimed.

In addition possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (*Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406). In the instant case the 21612-polynucleotides has been defined only by a statement of function of short chain alcohol dehydrogenase activity, which conveyed no distinguishing information about the identity of the claimed DNA sequence,

Art Unit: 1636

such as its relevant structural or physical characteristics. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 79 is indefinite because it is unclear what are the "instructions for use" in this context.

The applicant argues that claim 77 specifically recites the essential steps of the method of detection and one skill in the art would recognize what is intended by the phrase "instructions for use in the method of claim 77".

However, this is not found persuasive because the scope of instructions for use is not limited to the subject matter of claim 77. For example, instructions can include additional products and methods that are not described in the instant specification.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sumesh Kaushal
December 13, 2002

Conferees

Jeffary Fredman (Primary Examiner)
Gary Benzion (SPE 1637)
Irem Yucel (SPE 1636)

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA

Remy Yucel
REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
Conferee

.....